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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,423	03/26/2004	Tenneille E. Ludwig	960296.00050	2623
26734 7590 05/11/2007 QUARLES & BRADY LLP 33 E. MAIN ST, SUITE 900 P.O. BOX 2113 MADISON, WI 53701-2113			EXAMINER BARNHART, LORA ELIZABETH	
			ART UNIT 1651	PAPER NUMBER 1
			MAIL DATE 05/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,423	Applicant(s) LUDWIG ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 9 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 2/21/07 to claim 8 have been entered. Claims 1-12 remain pending in the current application, of which claims 8, 9, and 12 are being considered on their merits. Prior art references not included with this Office action can be found in a prior action.

Specification

The amendments to the specification are acceptable.

Claim Rejections - 35 USC § 112

The rejection under 35 U.S.C. § 112, second paragraph, is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, and 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Price et al. (2002, U.S. Patent Application Publication 2002/0076747).

Price teaches a composition comprising a culture plate; a nutrient medium (paragraph 128) therein; and mouse embryonic stem cells (ES-D3 cells) (Example 1, paragraphs 129-133). Price does not exemplify a composition comprising nutrient medium of 330 or 350mOsm or a composition comprising human ES cells. Price does teach, however, that the osmolarity of the medium may be "as high as about 350mOsm" (paragraph 101) and that said medium may be used to culture human ES cells (paragraph 102).

The selection of osmolarity of the medium of Price would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Price et al. teach that the osmolarity may be up to about 350mOsm. The selection of the source of ES cells in the Example of Price would also have been a routine matter of optimization on the part of the skilled artisan, said artisan recognizing that Price teach that ES cells may be obtained from humans and cultured in the medium of their invention. A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that Price teaches that the maximum preferable osmolarity for their medium is 310mOsm, so Price teaches away from increasing the osmolarity to the

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claimed level (Reply, page 7, paragraph 3). Applicant alleges that Price is not enabling (Reply, page 8, paragraph 1). Applicant alleges that Price provides insufficient support to make a culture of human stem cells as claimed (Reply, page 8, paragraph 2). These arguments have been fully considered, but they are not persuasive.

Patents are relevant as prior art for all they contain. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Nonpreferred embodiments constitute prior art. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See M.P.E.P. §2123. Therefore, the fact that Price does not teach that 350mOsm is a "preferred" medium osmolarity does not constitute a teaching away from this value. Price explicitly teaches that the osmolarity of their medium may be up to 350mOsm (paragraph 0101), so optimization within the explicitly stated range of Price would have been routine at the time of the invention.

It is acknowledged that the prior art as a whole must suggest the desirability of the invention, but a finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggest that the combination claimed is the preferred, or most desirable combination. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from the claimed invention because such disclosure does not criticize, discredit, or other wise discourage the solution claimed in the patent application. See *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1411 (2004).

In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court determined that motivation to combine prior art references need not be explicitly stated in the cited prior art; rather, the Court reiterated the standard set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 [148 USPQ 459], which required determining the scope of the prior art, ascertaining differences between the prior art and the instant claims; and resolving the level of ordinary skill in the pertinent art to determine the obviousness or nonobviousness of the claimed invention. In *KSR*, the Court reiterated the standard for overcoming obviousness rejections initially set forth in *Graham v. Deere*, namely convincing arguments that the cited art is non-analogous, a showing that the prior art teaches away from the claimed invention, or a showing of secondary considerations, e.g. truly unexpected results (see *KSR* at 1399). “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success,

it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103" (see *KSR* at 1397). In this case, Price explicitly teaches that the osmolarity of the medium may be up to 350mOsm (paragraph 0101). Applicants have provided no evidence that the medium of Price in which osmolarity has been adjusted above 330mOsm would be unsuitable for human stem cells, and in light of the explicit teaching of Price that the osmolarity may be increased to this degree, applicant's arguments are insufficient to overcome the *prima facie* case of obviousness.

Regarding the list of cells in paragraph 0102, again, applicant seems to be arguing that the fact that the medium of Price is described as being useful for culturing many different cell types constitutes a teaching away from culturing human cells specifically. Applicant's points regarding the needs of cells isolated from different mammals are noted; however, no evidence has been provided that the medium of Price (with osmolarity adjusted to a level in excess of 330mOsm) would be unsuitable for culturing human ES cells. In light of the *KSR* decision, and taking into consideration Price's explicit teaching that the osmolarity of their medium may be in excess of 330mOsm as instantly claimed, a substantive evidentiary showing of unexpected results is required to overcome this rejection.

No claims are allowed. No claims are free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart



SANDRA E. SAUCIER
PRIMARY EXAMINER

